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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/626,374 | 07/24/2003 | Ernest J. Lee | 01038/2/US | 1215 |
| 26648 | 7590 | 11/26/2004 | EXAMINER | |
| PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006 | | | TSOY, ELENA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1762 | |

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,374

Applicant(s)

LEE ET AL.

Examiner

Elena Tsoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/20/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

Amendment filed on October 20, 2004 has been entered. Claims 1-16 are pending in the application. Claim 16 is withdrawn from consideration as directed to a non-elected invention.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15 in the reply filed on October 20, 2004 is acknowledged. The traversal is on the ground(s) that subject matter of claim 16 is a product of the method of claim 1. This is found persuasive, and, therefore, claim 16 is joined Group I.

Specification

1. Objection to the disclosure because of the informalities has been withdrawn due to amendment.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6 and 8 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record as set forth in Paragraph No. 3 of the Office Action mailed on June 21, 2004.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7, 10-11, 13-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie et al. (4,600,645) for the reasons of record as set forth in Paragraph No. 14 of the Office Action mailed on June 21, 2004.
6. Claims 8-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie in view of Heimlich et al. (2003/0129236) for the reasons of record as set forth in Paragraph No. 15 of the Office Action mailed on June 21, 2004.
7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie et al. (4,600,645) for the reasons of record as set forth for claim 1 in Paragraph No. 14 of the Office Action mailed on June 21, 2004 because it relates to a product made by the method of claim 1.

Response to Arguments

8. Applicants' arguments filed October 20, 2004 have been fully considered but they are not persuasive.

(A) Applicants argue that the Office Action failed to establish *prima facie* case of obviousness over Ghebre-Sellassie because, in contrast to claimed invention, Ghebre-Sellassie uses two different coating solutions for first and second coats. Specifically, the first coating of Ghebre-Sellassie is a matrix of ethylcellulose colloidal particles dispersed in water that can include as additives "inert solids", e.g. clays while the second coating of Ghebre-Sellassie is a matrix of one or more hydrophilic preferably highly water-soluble polymer materials, a matrix that can include hydrophobic polymers such as HPMC (col. 2, lines 40-45).

The Examiner respectfully disagrees with this argument. First of all, in contrast to Applicants' argument, Ghebre-Sellassie clearly teaches that, although the use of hydrophilic matrices in a second coating is *preferred*, **non-hydrophilic matrices**, e.g. *water-insoluble ethyl cellulose* dispersed in water (See column 3, line 39) may be used in combination with suitable amounts of inert solids such as talc, kaolin (See column 3, lines 46-54). Secondly, Ghebre-Sellassie teaches nowhere that coating solutions for first and second coats should be different. In fact, the second coating composition may (or may not) comprise the same components as the first coating composition, e.g. water-insoluble ethylcellulose (See column 3, lines 5-6, 51-52), water-soluble hydrophilic polymer (See column 3, lines 16, 41), and the same inert solids such as talc and kaolin (See column 3, lines 11-14, 53).

(B) Applicants argue that Heimlich et al do not constitute prior art because filing date of Heimlich et al of 12/19/2002 is after priority date of the present application.

The Examiner respectfully disagrees with this argument. The effective filing date of Heimlich et al is not of 12/19/2002, but 12/20/2001, which is the filing date of provisional application 60/342,642, which has proper support for the subject matter on page 16, lines 5-12 (See MPEP 706.02 (f)(1), example 2, page 700-29).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762

ELENA TSOY
PRIMARY EXAMINER
ETsoy

November 23, 2004